

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year)	<b>See form PCT/ISA/210</b>
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Applicant's or agent's file reference <b>BCT040127/EN/DBO</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below	
International application No. <b>PCT/FR2004/002158</b>	International filing date (day/month/year) <b>18.08.2004</b>	Priority date (day/month/year) <b>20.11.2003</b>	
International Patent Classification (IPC) or both national classification and IPC <b>A61 K9/28, C09D103/00, C09D103/02</b>			
Applicant <b>ROQUETTE FRERES</b>			

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☐

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

## International application No.

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	<u>4, 8-12</u>	YES
	Claims	<u>1-3, 5-7, 13-18</u>	NO
Inventive step (IS)	Claims	<u>4, 8-12</u>	YES
	Claims	<u>1-3, 5-7, 13-18</u>	NO
Industrial applicability (IA)	Claims	<u>1-18</u>	YES
	Claims	<u>                    </u>	NO
<b>2. Citations and explanations:</b>			
Reference is made to the following documents:			
D1: WO 00/36006 A (FOOD & PACKAGING CENTRE MANAGEMENT LIMITED; YU, LONG; CHRISTIE, GREGOR) 22 June 2000 (2000-06-22)			
D2: US-A-5 498 706 (FRISCHE ET AL) 12 March 1996 (1996-03-12)			
D3: EP-A-1 245 577 (ROQUETTE FRERES) 2 October 2002 (2002-10-02)			
<b>1. Novelty (PCT Article 33(2))</b>			
The present application fails to comply with the requirements of PCT Article 33(1) since the subject matter of <b>claims 1-3, 5-7, 9, 11, 17 and 18</b> does not meet the requirement of novelty defined in PCT Article 33(2). <b>Document D1</b> describes (the references between parentheses apply to this document): a composition containing a starch (amylose) modified by means of a hydroxyalkylation reaction, another starch which may be derived from pea (page 3, lines 33-34), a film-forming polymer (polyvinyl alcohol or polyvinyl acetate), a polyhydroxylated plasticizer, a fatty acid and, optionally, water. This composition is used for the manufacture of flexible and biodegradable sheets and films. Specific examples of such			

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

compositions are given in examples 1-26. Examples 12 and 13 relate to compositions containing 24% of hydroxypropylated amylose and 57% of wheat starch (example 12), and 16% of hydroxypropylated amylose and 65% of wheat starch (example 13). These two compositions also contain polyvinyl alcohol and glycerol. The wheat starch contains approximately 25% of amylose, which gives an amylose percentage relative to the total amount of starch of approximately 47% for example 12 and 40% for example 13.

The subject matter of claims 1, 2, 5-7 and 18 is thus not novel (PCT Article 33(2)).

**Document D2** describes (the references between parentheses apply to this document): a composition containing pea starch modified by acetylation and ethyl citrate as plasticizer for forming a transparent and flexible sheet (example 2).

The subject matter of claims 1-3, 5, 6, 17 and 18 is thus not novel (PCT Article 33(2)).

**Document D3** describes (the references between parentheses apply to this document): the use of a pregelatinized high amylose starch stabilized by acetylation or hydroxypropylation, as a mixture with a high amylopectin waxy starch for the manufacture of films (flavouring sheet) and of soft gelatin capsules and hard gelatin capsules, and for the film-coating of various dietary or pharmaceutical supports (tablets) (page 3, lines 26-30; page 3, lines 48-50; page 3, line 56 - page 4, line 16). The film comprises, in terms of solids, 5 to 40% of high amylose starch and 40 to 80% of high amylopectin starch. Example 3 shows such a composition also containing glycerol. Maltodextrins, gelatins, pullulan, plant gums

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and gluten are also mentioned as secondary film-forming agents (page 3, line 56 - page 4, line 1).

The subject matter of claims 1, 5, 6, 7 and 13-18 is thus not novel (PCT Article 33(2)).

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Box No. VIII      Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**Clarity (PCT Article 6)**

The application fails to comply with the requirements of PCT Article 6 since claims 1, 3, 8 and 9 are not clear. The term "stabilized" used in said claims is vague and equivocal, and casts doubt on the meaning of the technical feature to which it refers. The subject matter of said claims is thus not clearly defined.